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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,530	05/09/2001	Kurt Klimpel	15280-290110	7146
20350	7590	12/09/2003	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/853,530	Applicant(s) KLIMPEL ET AL.	
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1644

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/6/2003 has been entered.

2. Claims 1-6 are under consideration. Claim 1 has been amended.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (WO 94/18332). Applicants arguments have been considered and deemed not persuasive.

Leppla et al. teach anthrax protective antigen (see last paragraph page 25 and first paragraph, page 26) and a fusion protein containing the PA binding domain of LF/growth factor, wherein growth factors are full length proteins(see last paragraph page 25 and second paragraph, page 26). Leppla et al. teach that the fusion protein can contain the first 1-254 amino acids of LF (e.g. PA binding domain)(see pages 6 and

7). The name anthrax as used by Leppla et al. refers to *Bacillus anthracis* (see last paragraph page 3, continued on next page). Processed protective antigen is created when the anthrax protective antigen is administered in vivo. Leppla et al. teach that the LF/fusion protein and PA are administered as a pharmaceutical composition (see page 27) containing saline (aqueous solution of physiologically compatible salts, see page 28). Leppla et al. do not teach the molar ratio recited in claim 1. Leppla et al. teach that the amount of PA and LF/fusion protein will be optimized using routine procedures. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Leppla teach the claimed invention except for the molar ratio recited in claim 1 and Leppla et al. teach that the amount of PA and LF/fusion protein will be optimized using routine procedures. The recitation of an intended use in this product claim carries no patentable weight because the claimed product is the same as the product rendered obvious in the instant rejection. The dosage recited in the claims (as per defined in page 20, penultimate paragraph of the specification) is encompassed by the dose range disclosed in page 27, lines 24-25 of Leppla et al.

Regarding applicants comments, the specification discloses on page 20 that:

For each recipient, the total vaccine amount necessary can be deduced from protocols for immunization with other vaccines. The exact amount of such antigen- APABP and PA compositions required will vary from subject to subject, depending on the species, age, weight and general condition of the subject, the particular fusion protein used, its mode of administration, and the like. Generally, dosage will approximate that which is typical for the administration of other vaccines, and will preferably be in the range of about 10 ng/kg to 1 mg/kg.

Thus, regarding the dosage recited in the claims, said dosage will vary according to the antigen and particular parameters as per stated above. Said passage also discloses a general range of antigen to be used. Leppla et al., disclose administration of the instant invention at a dosage that overlaps that encompassed by the limitation now recited in the claims (see page 27, lines 24-25).

Art Unit: 1644

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644



RONALD D. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 1600